

Office of Drug Enforcement and Program Compliance
49 CFR Part 40 Interpretation

Question: Can a urine specimen collection site be constructed to have two or more collectors or must each collection "station" be physically separated by a barrier or wall to ensure modesty and privacy of the donor?

Response: Sections 40.25(a)(2) and (3) states *"...A designated collection site shall be a location having an enclosure within which private urination can occur, a toilet for completion of urination, and a suitable clean surface for writing..."* and *"...If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply. The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer..."*

In specifying privacy and security of the collection site, the Department was concerned that the act of urination by a donor would have maximum privacy under most circumstances and that the specimen sample would be under sufficient security to prevent any allegation of tampering. Additionally, the regulatory requirement exists that the collection site person would have only one donor under his/her supervision at any one time. In other words, one collection site person may not process the paperwork or collect a specimen from more than one donor at a time. There are collection sites, particularly at health clinics, that may have "stations" or booths which are partially partitioned from each other or from the rest of the clinic. The collection site person usually gathers relevant information from the donor at the booth, completes the necessary paperwork, and escorts the donor to a toilet area where the donor can provide a specimen in privacy.

The rule permits no unauthorized personnel in any part of the designated collection site where urine specimens are collected or stored. In the multiple booth situation another collection site person would not be considered an unauthorized person. However, when other donors are present in a waiting area or another donor is being processed by another collection site person, the integrity of the specimen must be ensured. During the collection process, the collection site person must ensure that the specimen is under the direct control of the collection site person from the time the specimen is provided by the donor to the time it is sealed in the mailer. Additionally, regardless of the physical configuration of the collection site, there is the expectation that the donor will have some semblance of aural and visual privacy. For example, a donor may tell the collector that he/she is suffering from a particular illness, is on medication, or that he/she has an indwelling catheter, and wonder if this will impact on the test results. The donor should be able to make these statements without embarrassment or concern that another individual (i.e., another collector or donor) may overhear or see what the donor is providing to the collector.